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§573.940

labeled. Production controls shall include analysis sufficient to adequately monitor quality.

(e) The label or labeling of any selenium premix shall bear adequate directions and cautions for use including this statement: "Caution: Follow label directions. The addition to feed of higher levels of this premix containing selenium is not permitted."

(f) The additive is orally administered to beef and dairy cattle as an osmotically controlled, constant release bolus containing sodium selenite. Each bolus contains 360 milligrams of selenium as sodium selenite, and delivers 3 milligrams of selenium per day for 120 days. To ensure safe use of the additive:

(1) The osmotically controlled, constant release bolus is for use only in beef and dairy cattle more than 3 months of age or over 200 pounds body weight.

(2) Only one bolus containing 360 milligrams of selenium as sodium selenite is administered orally to each animal in 120 days.

(3) The labeling shall bear the following: "This bolus delivers the maximum daily allowable amount of selenium and shall be the sole source of supplementation. Do not use in areas containing excess selenium. Do not rebolus within 4 months."

(52 FR 10398, Apr. 6, 1987; 52 FR 21001, June 4, 1987, as amended at 54 FR 14215, Apr. 10, 1989; 54 FR 15874, Apr. 19, 1989)

EFFECTIVE DATE NOTE: At 53 FR 47973, Sept. 13, 1993, the amendments to §573.920 that were published at 52 FR 10387, Apr. 6, 1987; 52 FR 21001, June 4, 1987; and 54 FR 14214, Apr. 10, 1989 were stayed until further notice. At 59 FR 45973, Sept. 6, 1994, the stay was confirmed.

§573.940 Silicon dioxide.

The food additive silicon dioxide may be safely used in animal feed in accordance with the following conditions:

(a) The food additive is manufactured by vapor phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect.

(b) It is used or intended for use in feed components as an anticaking agent, and/or grinding aid, as follows:

21 CFR Ch. I (4-1-95 Edition)

Feed component	Limitations (percent)
BHT (butylated hydroxytoluene)	2
Methionine hydroxy analog and its calcium salts	1
Piperazine, piperazine salts	0.5
Sodium propionate	1
Urea	1
Vitamins	3

(c) It is used in feed as an anticaking agent in an amount not to exceed that reasonably required to accomplish its intended effect and in no case in an amount to exceed 2 percent by weight of the finished feed.

§573.960 Sorbitan monostearate.

The food additive sorbitan monostearate may be safely used alone or in combination with polysorbate 60 as an emulsifier in mineral premixes and dietary supplements for animal feeds.

§573.980 Taurine.

The food additive taurine (2-aminoethanesulfonic acid) may be safely used in feed in accordance with the following prescribed conditions:

(a) It is used as a nutritional supplement in the feed of growing chickens.

(b) It is added to complete feeds so that the total taurine content does not exceed 0.054 percent of the feed.

(c) To assure safe use of the additive, the label and labeling shall bear in addition to the other information required by the Act:

- (1) The name of the additive.
- (2) The quantity of the additive contained therein.
- (3) Adequate directions for use.

§573.1000 Vexxite.

The food additive vexxite may be safely used in animal feed in accordance with the following prescribed conditions:

(a) The additive is a magnesium-aluminum-iron silicate conforming to one of the following:

(1)(i) Vexxite granules: The additive contains a minimum of 98 percent of hydrobiotite; it is thermally expanded and has a bulk density of from 5 to 9 pounds per cubic foot.

(ii) It is used or intended for use:

(a) In poultry feed at a level not to exceed 5 percent of the weight of the finished feed as a nonnutritive bulking

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agent for restricting caloric pullet replacement feeds.

(b) As an anticaking agent, pelleting aid, or carrier for the incorporation of nutrients in poultry, swine, dog and cat feeds, in an amount not that necessary to accomplish intended effect and in no case 1.5 percent of the dog feed or of the final feed for other animals.

(2)(i) Vexxite flakes: The additive contains a minimum of 98 percent hydrobiotite; it has a bulk density of from 20 to 30 pounds per cubic foot.

(ii) It is used or intended as an anticaking or bleeding agent in animal feeds in an amount not that necessary to accomplish intended effect and in no case 1 percent by weight of the feed for ruminants.

(3)(i) Vexxite grits: The additive contains a minimum of 98 percent hydrobiotite; it has a bulk density of from 40 to 50 pounds per cubic foot.

(ii) It is used or intended as a partial roughage replacement in animal feeds in an amount not that necessary to accomplish intended effect and in no case 1 percent by weight of the feed.

(b) To assure safe use of the additive, the label of any feed additive, feed additive concentrate, additive premix, or complete feed therefrom shall bear, in addition to the other information required by the Act, the name of the additive (vexxite granules, vexxite flakes, vexxite grits), adequate directions for use, and, when the additive is used in excess of 1 percent, a statement of the quantity of the additive therein and the term "nonnutritive bulking agent" in juxtaposition therewith.

§573.1010 Xanthan gum.

The food additive xanthan gum may be safely used in animal feed in accordance with the following:

(a) The food additive is xanthan gum as defined in §172.895 of this chapter and meets all of the specifications thereof.

(b) It is used or intended as a stabilizer, emulsifier, thickening agent, or bodying agent in animal feed as follows:

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Feed component	Limitations (percent)
HIT (butylated hydroxytoluene)	2
lithionine hydroxy analog and its calcium salts	1
iperazine, piperazine salts	0.8
odium propionate	1
ros	1
hamine	3

(c) It is used in feed as an anticaking agent in an amount not to exceed that reasonably required to accomplish its intended effect and in no case in an amount to exceed 2 percent by weight of the finished feed.

§578.980 Sorbitan monostearate.

The food additive sorbitan monostearate may be safely used alone or in combination with polysorbate 60 as an emulsifier in mineral premixes and dietary supplements for animal feeds.

§578.990 Taurine.

The food additive taurine (2-aminoethanesulfonic acid) may be safely used in feed in accordance with the following prescribed conditions:

(a) It is used as a nutritional supplement in the feed of growing chickens.

(b) It is added to complete feeds so that the total taurine content does not exceed 0.054 percent of the feed.

(c) To assure safe use of the additive, the label and labeling shall bear in addition to the other information required by the Act:

(1) The name of the additive.

(2) The quantity of the additive contained therein.

(3) Adequate directions for use.

§578.1000 Verxite.

The food additive verxite may be safely used in animal feed in accordance with the following prescribed conditions:

(a) The additive is a magnesium-aluminum-iron silicate conforming to one of the following:

(1)(i) Verxite granules: The additive contains a minimum of 98 percent of hydrobiotite; it is thermally expanded and has a bulk density of from 5 to 9 pounds per cubic foot.

(ii) It is used or intended for use:

(c) In poultry feed at a level not to exceed 5 percent of the weight of the finished feed as a nonnutritive bulking

agent for restricting calorie intake in pullet replacement feeds.

(b) As an anticaking or blending agent, pelleting aid, or nonnutritive carrier for the incorporation of nutrients in poultry, swine, dog, or ruminant feeds, in an amount not to exceed that necessary to accomplish its intended effect and in no case to exceed 1.5 percent of the dog feed or 5 percent of the final feed for other animals.

(2)(i) Verxite flakes: The additive contains a minimum of 98 percent of hydrobiotite; it has a bulk density of from 20 to 30 pounds per cubic foot.

(ii) It is used or intended for use as an anticaking or blending agent in ruminant feeds in an amount not to exceed that necessary to accomplish its intended effect and in no case to exceed 1 percent by weight of the final feed for ruminants.

(3)(i) Verxite grits: The additive contains a minimum of 80 percent of hydrobiotite; it has a bulk density of from 40 to 50 pounds per cubic foot.

(ii) It is used or intended for use as a partial roughage replacement in ruminant feeds in an amount not to exceed that necessary to accomplish its intended effect and in no case to exceed 1 percent by weight of the final feed.

(b) To assure safe use of the additive, the label of any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom shall bear, in addition to the other information required by the Act, the name of the additive (verxite granules, verxite flakes, or verxite grits), adequate directions for use, and, when the additive is present in excess of 1 percent, a statement of the quantity of the additive contained therein in the term "nonnutritive" in juxtaposition therewith.

§578.1010 Xanthan gum.

The food additive xanthan gum may be safely used in animal feed as follows:

(a) The food additive is xanthan gum as defined in §172.695 of this chapter and meets all of the specifications thereof.

(b) It is used or intended for use as a stabilizer, emulsifier, thickener, suspending agent, or binding agent in animal feed as follows:

(1) In calf milk replacers at a maximum use level of 0.1 percent, as fed.

(2) In liquid feed supplements for ruminant animals at a maximum use level of 0.25 percent (5 pounds per ton).

(c) To assure safe use of the additive:

(1) The label of its container shall bear, in addition to other information required by the act, the name of the additive.

(2) The label or labeling of the additive container shall bear adequate directions for use.

[49 FR 44630, Nov. 8, 1984]

§578.1020 Yellow prussiate of soda.

Yellow prussiate of soda (sodium ferrocyanide decahydrate: $\text{Na}_4\text{Fe}(\text{CN})_6 \cdot 10\text{H}_2\text{O}$) may be safely used as an anticaking agent in salt for animal consumption at a level not to exceed 13 parts per million. The additive contains a minimum of 99.0 percent by weight of sodium ferrocyanide decahydrate.

[41 FR 38697, Sept. 10, 1976; 41 FR 48100, Nov. 2, 1976]

PART 579—IRRADIATION IN THE PRODUCTION, PROCESSING, AND HANDLING OF ANIMAL FEED AND PET FOOD

Subpart A—General Provisions

Sec.

579.12 Incorporation of regulations in part 179.

Subpart B—Radiation and Radiation Sources

579.22 Ionizing radiation for treatment of laboratory animal diets.

AUTHORITY: Secs. 201, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 343, 348, 371).

Subpart A—General Provisions

§579.12 Incorporation of regulations in part 179.

Regulations providing for irradiation in the production, processing, and handling of food in part 179 of this chapter are incorporated in subchapter B as applicable to use in the production, processing, handling, and labeling of ani-